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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,346	06/28/2001	Wayne D. Comper	48643-015	2638

7590 09/29/2006

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/893,346	COMPER, WAYNE D.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,9-14,16,17,20,22,23 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,9-14,16,17,20,22,23 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 6/14/06. SBC 9/28/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on April 28, 2006 and July 19, 2006 are acknowledged and entered. Claims 8 and 26 have been cancelled, rendering any rejections thereof moot. Claims 1-5, 7, 9-14, 16, 17, 20, 22, 23 and 25 are pending and examined.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicant's amendment.

The rejection of claims 1-5, 7-14, 16-17, 20, 22, 23 and 25 under 35 U.S.C. 102(b) as anticipated by Trevisan *et al.* (*American Journal of Hypertension*, 1995, 8:876-883) is withdrawn in view of Applicant's amendment. The claims as amended recite additional method steps in determining protein content which Trevisan *et al.* does not disclose or fairly suggest.

Claim Rejections - 35 USC § 112

Claims 1-5, 7, 9-14, 16, 17, 20, 22, 23 and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification is only enabling for some of the claimed embodiments. The specification is enabled for a method of assessing therapeutic effectiveness of a treatment agent for renal disease and/or renal complications of a disease or condition, comprising assaying for

total albumin protein content via HPLC compared with total albumin protein content via radioimmunoassay using antibodies to native albumin. The specification is not enabling for a method of assessing therapeutic effectiveness of a treatment agent for renal and/or renal complications of a disease or condition, comprising assaying for any protein (non-albumin) via the steps claimed. This rejection was previously made of record and withdrawn, however, upon further consideration of the claimed invention, the rejection is reinstated in this Office action.

The breadth of the claims encompasses the assessment of therapeutic effectiveness of a treatment agent for renal disease and/or renal complications of a disease or condition, wherein any protein can be measured in terms of total protein content (native and intact-modified). The nature of the invention is the identification of intact-modified protein present in the urine, indicative of problems with the processing of proteins through the kidneys. The state of the art demonstrates that Applicant has successfully characterized immunochemically nonreactive urinary albumin using HPLC (Osicka and Comper, *Clinical Chemistry*, 2004, 50(12):1-6, cited in the affidavit filed October 4, 2004).

The level of skill in the art is high, evidenced by the inventor and those in the field cited in the references of the information disclosure statements and the instant specification. The level of predictability in the art with regard to identifying intact-modified protein present in urine in patients with renal disease/complications is limited to identification of albumin. The specification does not provide guidance for identifying other intact-modified proteins other than albumin that are present in urine in patients with renal disease/complications. While such intact-modified albumin has been demonstrated as indicative of renal disease/complications, no other

protein in humans has been identified as intact-modified *and* indicative of renal disease/complication.

The Office offers the following scenario as an example of how the specification fails to enable for the full scope of the invention. Patient X is diagnosed with leprosy. Patient X's physician (one skilled in the art) suspects that there may be renal disease/complications as a result of leprosy and decides to use Applicant's method for determining a treatment for the renal disease/complications. The physician must choose a protein to monitor. Based on the disclosure, the only protein to monitor is albumin. Although the claims indicate that one may detect a number of proteins, of what use is detecting globulin, or transferrin, or lipoprotein, or insulin, or lactate dehydrogenase? The specification does not demonstrate that globulin, or any other protein is present in the intact modified form in patients with renal disease/complications. Given that the disclosure only offers a hypothesis on how albumin becomes intact/modified, one would not be able to assume that that hypothesis relates to globulin or any other protein until a mechanism is understood. While a mechanism is not required to practice the invention with albumin being the monitored protein, extrapolating data from albumin to other proteins without understanding the mechanism or doing any experimentation on other proteins is not reliable.

With regard to the identification of intact-modified proteins via HPLC, it is understood that once the intact-modified proteins from the patient are identified via HPLC, one would be able to make antibodies that specifically bind to those intact-modified proteins. However, one would expect that the intact-modified proteins would be patient-specific and not useful for detecting intact-modified protein from a different patient. Therefore, the initial step in detecting

total protein content must include a step of HPLC, since known antibodies to native albumin have been shown to be non-reactive with intact-modified urinary albumin.

Given the breadth of the claims, the nature of the invention, the high level of skill in the art, the state of the art, the low level of predictability, the limited guidance and examples in the specification relating to intact-modified albumin, the full scope of the claims is not enabled.

Conclusion

No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 9/28/06

STACY B. CHEN
PRIMARY EXAMINER